



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,869	10/07/2004	Russell Heinrich	2799	6233
Covidien 60 Middletown Avenue North Haven, CT 06473			EXAMINER EREZO, DARWIN P	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 07/31/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,869	Applicant(s) HEINRICH ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 26-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/10/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in page 2, paragraph 2, of the reply filed on 4/28/08 is acknowledged.
2. The applicant further contradicts the election without traverse (prejudice) by stating that there would not be a burden to the examiner to examine the application as a whole. This argument is not persuasive because the non-elected inventions do not share the same special technical features. Therefore, it would be a burden to the examiner to search for each special technical feature that is not cited in the elected Group I.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 26-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/28/08.

Information Disclosure Statement

4. The information disclosure statement(s) (IDS) submitted on 12/10/04 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Drawings

5. The drawings filed on 10/07/04 are acceptable.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4, 6, 8, 9, 11, 12, 15-17, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,176,864 to Chapman.

Claims 1 and 15: Chapman disclose a device for joining a first body vessel to a second body vessel (anastomosis device), comprising: a concentric inner member **20** having a distal end portion and defining a longitudinal axis; a concentric outer member **40** defining a lumen dimensioned to receive the inner member therein; and a radially expandable anchor **30** disposed at the distal end of the inner member, the expandable anchor having an initial condition wherein the expandable anchor is disposed between the outer member and the inner member (Fig. 4) and an expanded condition wherein the expandable anchor is radially larger than the expandable anchor in the initial condition (Fig. 3);

Claims 2 and 16: The expandable anchor is made from a foam-like material (col. 5, ll. 36-45)

Claims 4, 17 and 20: The distal end portion of the expandable anchor is shown to be radially larger than a proximal end portion of the expandable anchor when in the expanded condition (Fig. 9) to prevent removal of the anastomosis device, and wherein the expandable anchor has a thin-walled cylindrical shape when in the initial condition.

Claims 6 and 8: The inner member is an inner tubular sleeve defining a central lumen extending therethrough, which permits liquid to pass therethrough and drain through the inner tubular sleeve.

Claims 9 and 21: The expandable anchor is a hollow tube that defines at least one longitudinally oriented passage extending completely therethrough when in the expanded condition.

Claims 11 and 12: Graft member **10** is everted over a portion of a distal end of the expandable anchor and the inner member, wherein the graft member is viewed as sheath disposed about the expandable anchor for defining the shape of the expandable anchor when in the expanded condition. The graft can member can also be viewed as being indirectly connected to the distal end of the tubular sleeve and act as grasper to the interior surface of the vessel **12**.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 3 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman, as applied to the rejections above, and in view of US 2,898,913 to Ritter et al.

Chapman discloses all the limitations of the claims except for the expandable anchor having a frustoconical shape when in the expanded condition. However, Ritter discloses that using connectors with frustoconical shapes are well known in the art, as seen in Fig. 3. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Chapman to have a frustoconical shape since it is well known in the art, as shown by Ritter, and since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

12. Claims 5, 13, 14, 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman, as applied to the rejections above, and in view of US 5411,520 to Nash et al.

Chapman discloses all the limitations of the claims except for the expandable anchor radially expands upon contact with moisture. Instead, Chapman discloses a self-expanding foam-like expandable anchor. However, the use of foam expanded by fluid is well known in the art. For example, Nash discloses an expanding foam plug that expands in the presence of blood. Thus, the self expanding foam of Chapman and the foam expandable in the presence of blood are well known foam expandable equivalents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the foam of Chapman for the foam of Nash because it has been held that a substituting one known element for another equivalent element will yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

It is also noted that the foam taught by Chapman is collagen, which is a known bioabsorbable material that is absorbed over time.

13. Claims 7 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman, as applied to the rejections above, and in view of US 6,241,743 to Levin et al.

Chapman discloses all the limitations of the claimed invention except for the inner tubular sleeve includes a region near its distal end which is porous. However, Levin discloses another anastomosis device having a structure 12 defining pores in

order to provide the graft flow based nutrition (col. 5, ll. 62-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide pores in the distal end of the inner tubular sleeve of Chapman since it would provide flow based nutrition to the everted graft at the distal end.

14. Claim 10 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chapman.

With regards to the limitation that the device further comprises a control unit, remotely located, for operating the anastomotic device, it would have been inherent for the device of Chapman to have a control unit in order to manipulate the device. If this is not found persuasive, then it would have been obvious to one of ordinary skill in the medical art to provide a control unit to the device of Chapman in order to remote control the deployment of the expandable anchor.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773